THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte EDWARD TEEPLE, JR.

Appeal No. 97-0943
Application No. 08/232,502[1]

ON BRIEF

Before CALVERT, FRANKFORT, and NASE, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1, 2, 5 through 7, 9, 10 and 33 through

[1] Application for patent filed April 25, 1994. According to the appellant, the application is a continuation of Application No. 07/986,189, filed December 7, 1992, now abandoned.

35.[2] Claims 11, 12, 15 through 21, 24, 25 and 27 through 32 have been withdrawn from consideration under 37 CFR § 1.142(b) as being drawn to a nonelected invention. Claims 3, 4, 8, 13, 14, 22, 23 and 26 have been canceled.

We AFFIRM, however, for reasons explained infra, we have denominated our affirmance a new ground of rejection under 37 CFR § 1.196(b).

BACKGROUND

The appellant's invention relates to a method of preparing a drug solution. Claim 1 is representative of the subject matter on appeal and a copy of claim 1 is attached to this decision.

The prior art references of record relied upon by the examiner as evidence of obviousness under 35 U.S.C. § 103 are:

Rubalcaba, Jr. 4,898,578 Feb. 6, 1990

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[2] Claims 2, 5, 7 and 33 have been amended subsequent to the final rejection.

Hamacher 5,102,408 Apr. 7, 1992

Claims 1, 2, 5 through 7, 9, 10 and 33 through 35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the appellant regards as the invention.[3]

Claims 1, 2, 5 through 7, 9, 10 and 33 through 35 stand rejected under 35 U.S.C. § 103 as being unpatentable over Rubalcaba in view of Hamacher.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the § 103 and § 112, second paragraph, rejections, we make reference to the final rejection (Paper No. 7, mailed December 11, 1995) and the examiner's answer (Paper No. 13, mailed October 25, 1996)

[3] The examiner withdrew the specific objections to claims 2, 7 and 32 (sic, 33?) in the Advisory Action of April 1, 1996.

for the examiner's complete reasoning in support of the rejections, and to the appellant's brief (Paper No. 12, filed July 16, 1996) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

The indefiniteness issue

We sustain the rejection of claims 1, 2, 5 through 7, 9, 10 and 33 through 35 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the appellant regards as the invention, although not for the reasons specifically stated by the examiner.

According to the examiner (final rejection, pp. 2-4), it is not clear that claim 1 is claiming the method disclosed in the specification. Specifically, the examiner questioned why the concentration being determined in step C of claim 1 is based on the standardized rate range of infusion, not the maximum rate of infusion as set forth in the specification.

Claims are considered to be definite, as required by the second paragraph of 35 U.S.C. § 112, when they define the metes and bounds of a claimed invention with a reasonable degree of precision and particularity. See In re Venezia, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976).

Our review of claim 1 reveals that step C of claim 1 (i.e., "determining a required concentration of said at least one drug based on a patient's weight, said dosage rate, amount of said solution, and standardized rate range of infusion") fails to set forth the metes and bounds of the claimed invention with a reasonable degree of precision and particularity for the following reasons.

As set forth in the specification, the weight of the drug and hence its concentration is determinable when the specific dosage rate, body weight, rate of infusion and amount (i.e., volume) of solution are known. However, in step C of claim 1, the specific rate of infusion is not specified since step C refers to the standardized rate range of infusion established in step B of claim 1. Since the standardized rate range of infusion is a variable, it is not possible to determine the weight of the drug and hence its concentration. The appellant states (Amendment filed May 11, 1996, Paper No. 8, page 2) "the Examiner is correct in stating the maximum rate of infusion is used to calculate the concentration." However, step C of claim 1 does not recite that the maximum rate of infusion is used to calculate the concentration, instead step C of claim 1 incorrectly recites that the rate range of infusion is used to calculate the concentration.

Likewise, the specific amount (i.e., volume) of solution is not able to be specified since the drug has not yet been mixed in the infusion bag. We read the preamble of claim 1 to recite that the drug is part of the solution. Thus, the

specific amount (i.e., volume) of solution is not able to be specified until the drug is mixed. We recognize that in the appellant's disclosed method (specification, page 17) the drug is mixed with another fluid in the bag, that the known amount (i.e., volume) of the fluid in the bag is used to determine the amount (i.e., volume) of drug to be added to the fluid in the bag, that an amount (i.e., volume) of fluid is withdrawn from the bag equivalent to the amount (i.e., volume) of drug being added to the bag, and that thereafter the determined amount (i.e., volume) of drug is mixed with the remaining fluid in the bag. However, this is not the method recited in the appealed claims.

As to the examiner's lack of antecedent objections to claims 5 and 33, we believe the appellant's after final amendments (Paper No. 8) to claims 5 and 33 overcome those objections. However, the appellant failed to amend claim 34[4] to correct the antecedent objection. Additionally, we note that claim 34 lacks antecedent basis for "said anesthesia."

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[4] The amendment amended claims 32 and 33 (not claims 33 and 34) to delete "predetermined."

37 CFR § 1.196(b)

Inasmuch as the basic thrust of our affirmance of the 35 U.S.C. § 112, second paragraph rejection differs from the rationale advanced by the examiner for the rejection, we hereby designate the affirmance to be a new ground of rejection pursuant to 37 CFR § 1.196(b) to allow the appellant a fair opportunity to react thereto (see In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976)).

The obviousness issue

Considering now the rejection of claims 1, 2, 5 through 7, 9, 10 and 33 through 35 under 35 U.S.C. § 103, we have carefully considered the subject matter defined by these claims. However, for reasons stated supra, no reasonably definite meaning can be ascribed to certain language appearing in the claims. As the court in In re Wilson, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970) stated:

> All words in a claim must be considered in judging the patentability of that claim against the prior art. If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious --the claim becomes indefinite.

In comparing the claimed subject matter with the applied prior art, it is apparent to us that considerable speculation and assumptions are necessary in order to determine what in fact is being claimed. Since a rejection based on prior art cannot be based on speculation and assumptions, see In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962), we are constrained to reverse, pro forma, the examiner's rejection of claims 1, 2, 5 through 7, 9, 10 and 33 through 35 under 35 U.S.C. § 103. We hasten to add that this is a procedural reversal rather than one based upon the merits of the section 103 rejection.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1, 2, 5 through 7, 9, 10 and 33 through 35 under 35 U.S.C. § 103 is reversed and the decision of the examiner to reject claims 1, 2, 5 through 7, 9, 10 and 33 through 35 under 35 U.S.C. § 112, second paragraph is affirmed, with the affirmance constituting a new ground of rejection under 37 CFR § 1.196(b).

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53131, 53197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 37 CFR § 1.196(b)

IAN A. CALVERT Administrative Patent Judge	)
CHARLES E. FRANKFORT Administrative Patent Judge	) BOARD OF PATENT APPEALS AND INTERFERENCES
JEFFREY V. NASE Administrative Patent Judge	)

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APPENDIX

1. A method for preparing a solution with at least one drug for an infusion bag for providing continuous infusion into a patient, comprising the following steps:

a. determining a dosage rate for a maximum dosage at a standardized maximum rate of infusion for said drug;

b. establishing a standardized titration rate range of infusion;

c. determining a required concentration of said at least one drug based on a patient's weight, said dosage rate, amount of said solution, and standardized rate range of infusion; and

d. mixing said drug into a bag of said solution in the concentration determined in Step C.

APPEAL NO. 97-0943 - JUDGE NASE
APPLICATION NO. 08/232,502

APJ NASE

APJ FRANKFORT

APJ CALVERT

DECISION: **AFFIRMED**;
37 CFR § 1.196(b)

Prepared By: Delores A. Lowe

DRAFT TYPED: 09 Feb 98

FINAL TYPED: